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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,971	01/09/2002	Jean-Michel Scherrmann	DASI.002.03US	3468

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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,971	SCHERRMANN ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/22/02; 1/9/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of group V, claims 23-26 in the reply filed on 7/19/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/19/04.

3. Claims 23-26 are currently being examined in this application.

Priority

This application is a continuation of application 09/477,269, which is a continuation of application 09/139,536, which is a continuation of application 08/821,895.

Information Disclosure Statement

The Information Disclosure Statements filed on 10/22/02 and 1/9/02 have been fully considered and initialed by the examiner. It is noted that the Information Disclosure Statement filed on 4/16/02 is a copy of the Information Disclosure Statement filed on 1/9/02.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 23 recites a monoclonal antibody, which binds specifically to cocaine and cocaethylene and has or no cross reactivity to benzoylecgonine. Claim 24 recites that the monoclonal antibody according to claim 23, labeled with an agent capable of providing a detectable signal. Claim 25 recites that the monoclonal antibody has an affinity of at least 5 X 10^8 for cocaine and cocaethylene and the monoclonal antibody is of class IgG. Claim 26 recites a composition comprising the monoclonal antibody.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

The specification discloses methods of raising antibodies (polyclonal), which are specific to cocaine. The specification discloses that the antisera obtained by the methods should be IgG or equivalent in the particular host. Affinities for cocaine and/or cocaethylene will usually be at least about 5 X 10-^{8} , generally ranging upto 10^{-11}, generally in the range of 10^{-09} to 10^{-10}. The specification teaches generally known methods to raise monoclonal antibodies. The specification teaches that the antisera and monoclonal may be used in immuno assays. The specification teaches that 'by employing labeled antibodies, where the label provides for the production of a detectable signal, e.g., radioactivity, fluorescence, light absorption, etc., the amount of drug in the blood can be quantitated.' The specification has not disclosed any monoclonal antibodies,

which bind specifically to cocaine and are labeled with an agent. The specification has not have any working examples of the monoclonal antibodies, which are specific to cocaine, and labeled monoclonal antibodies. The specification discloses methods of immunization of mice and rabbits with the cocaethylene immuno conjugates, and tests to determine the specificity of the antibodies or antisera. The specification has not shown monoclonal antibodies obtained using the conjugates, and tests to determine the monoclonal antibodies are specific to cocaine or cocathylene and no cross reactivity to benzoyl ecgonine. The specification has neither disclosed monoclonal antibodies, which have affinity of 5×10^8 for cocaine or cocaethylene nor a composition comprising the monoclonal antibodies.

Disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. Noelle v. Lederman, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (holding there is a lack of written descriptive support for an antibody defined by its binding affinity to an antigen that itself was not adequately described.

The instant claim does not recite the specific structure of the cocaine or cocaethylene to which the monoclonal antibody raised was specific. The specification discloses specific cocaine or cocaethylene conjugates which are used in raising cocaine specific antibodies that do not cross-react with benzoylecgonine.

In the present instance, the claimed monoclonal antibodies which specifically bind to cocaine contains no identifying characteristics regarding the monoclonal antibodies or the structure of the cocaine or cocaethylene.

Additionally, the narrow scope of examples directed to specific cocaethylene conjugates, and antisera obtained using the conjugates, are clearly not representative of the scope of monoclonal antibodies or the composition comprising the monoclonal antibodies of the presently claimed invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The term "low or no cross reactivity" in claim 23 is a relative term which renders the claim indefinite. The term "low or no cross reactivity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification has not disclosed what range of cross reactivity is considered as low or no cross reactivity. The specification has not disclosed any monoclonal antibodies which has low or no cross reactivity to benzoylecgonine.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 23, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Yugawa et al (US Patent 6,174,723 B1).

The instant claim recites a monoclonal antibody, which binds specifically to cocaine and cocaethylene and has or no cross reactivity to benzoylecgonine.

Yugawa et al teach a method for preparing a cocaine-protein conjugate, and a method of producing monoclonal to cocaine using the conjugate (see the abstract). The reference discloses that the monoclonal antibodies have high affinity for cocaine, and specifically binds to cocaine. The reference teaches that the purified monoclonal antibody was IgG, and has affinity to cocaine is 10^9 M. The reference discloses that the monoclonal antibodies, and relative sensitivities for cocaine and its derivatives. The reference teaches that the monoclonal antibodies have low affinity binding to benzoylecgonine (i.e., see column 10). Thus, the reference clearly anticipates the claimed invention.

10. Claims 23, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Wirsching et al (US patent 6,383,490 B1).

The instant claim recites a monoclonal antibody, which binds specifically to cocaine and cocaethylene and has or no cross reactivity to benzoylecgonine, and the labeled monoclonal antibody and the composition comprising the monoclonal antibody.

Wirsching et al teaches methods for preparing cocaine immunogens, which are stable. The reference teaches that the benzoylecgonine (metabolite of cocaine) titer is detrimental, since the antisera would be inadequate in neutralizing cocaine, in presence of the stable metabolite (benzoylecgonine). The reference teaches the cocaine analogs and cocaine immunoconjugates

(i.e., see columns 3-5). The reference teaches method for obtaining anti-cocaine monoclonal antibodies (i.e., see column 14). The reference teaches monoclonal antibodies with high affinity and specificity for cocaine, and the antibodies have binding constants in the submicromolar range and were 10-1000 times more specific for cocaine versus cocaine metabolites (refers to the instant claim 23, 'has low or no cross reactivity to benzoylecgonine) (i.e., see column 8). The reference clearly anticipates the claimed invention.

11. Claims 23. 25 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,760,184 (Swain et al).

Swain et al teach hapten-carrier conjugates capable of eliciting anti-hapten antibodies in vivo. The reference teaches novel cocaine immuno conjugates. The reference teaches specificity of cocaine specific antibodies (i.e., see example 21). The reference teaches that the antibodies raised with immuno conjugate cocaine-BSA PS 5.6, effectively recognized norcocaine, cocaethylene, and recognized poorly the benzoylecgonine and ecgonine methyl ester (i.e., see column 38). The reference teaches a highly specific monoclonal antibody was raised from cocaine-BSA immunized animal which also displayed very similar specificity for cocaine, is 2000 times greater to cocaine than benzoylecgonine (refers to instant claim) (i.e., see column 38). The reference teaches that the antibodies has affinities ranging from 1×10^{-7} to -1×10^{-10} M. Thus, the reference clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US patent 5,760,184 (Swain et al), or US patent 6,383,490 B1 (Wirsching et al), or US Patent 6,174,723 B1 (Yugawa et al) and US Patent 5,340,748 (Baugher et al).

Swain et al, Wirsching et al and Yugawa et al have been discussed supra. The claimed invention differs from the prior art teachings by reciting that the monoclonal antibody is linked to an agent capable of providing a detectable signal. It would have been obvious to one skilled in the art to use the monoclonal antibodies specific to cocaine in diagnostic assay. Baugher et al teach assay reagents, devices, methods and kits used in the analysis of analytes. The reference teaches the anti-cocaine antibody was conjugated to alakaline phosphatase (refers to an agent of the instant claims) (i.e., see column 16). The reference teaches that the label of the indicator reagent is a substance capable of producing a signal detected by visual or instrumental means

(i.e., see column 7) (refers to an agent capable of providing a detectable signal of the instant claims). The reference in Example 1 teaches the enzyme immunoassay for cocaine. The reference teaches the anti-cocaine antibody was conjugated to alakaline phosphatase (i.e., see column 16) (refers to the instant claim 24), which is indicator reagent (refers to the instant claim 26 composition). The reference teaches the use of indicator reagent (anti-cocaine antibody composition) in cocaine immuno assay to detect the presence of cocaine in a sample (i.e., see columns 17-18). Thus, it would have been obvious to one skilled in the art at the time the invention was made to use the monoclonal antibodies specific to cocaine in immuno assay by conjugating or linking the antibody to an agent capable of generating the signal. A person skilled in the art would have been motivated to the use the monoclonal antibody specific to cocaine, and has low or no affinity to benzoylecgonine, because the monoclonal antibody would not cross react with benzoylecgonine and the results would be specific to cocaine.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

24 September 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER